III. Remarks

A. Status of the Application

Claims 12-21 and 31-40 were previously pending. No claims are added or canceled by the present paper. Applicants request reconsideration of the application in light of the following remarks.

B. Rejections under 35 U.S.C. §112

Claims 14-16 and 31-40 stand rejected under 35 U.S.C. §112, first paragraph. Specifically, the Office Action asserts that the specification does not enable one skilled in the art to use the invention commensurate with the scope of these claims. The Office Action states that "the specification, while being enabling for preparation of the vertebrae by possibly forming bores in the sidewall that receives the insertion members or screws, does not reasonably provide enablement for laterally forming slots in the first and second vertebrae." With respect to claims 31-40, the Office Action states that "[t]he disclosure does not describe the method of correcting spondylolisthesis as including the use of lateral screws and an elongate member or rod in combination with insertion of an implant between the vertebrae."

Applicants respectfully disagree. In general, the §112 rejections of claims 14-16 and 31-40 are all related to the disclosure of a method that includes both correcting spondylolisthesis from a lateral approach and inserting an implant between the vertebrae from a lateral approach. However, the "Lateral Correction" portion of the application at paragraphs [0072]-[0119] and Figs. 1-13 discloses exactly this combination. In particular, in the context of Figs. 2, 3a, and 3b describing the method of correcting spondylolisthesis with a pair of bone screws and a rod from a lateral approach, the specification explicitly notes that "Removal of the diseased or degenerated disc results in the formation of intervertebral space S between the upper and lower vertebrae V_U, V_L. In the present embodiment, it is desired to insert a prosthetic joint into the intervertebral space S." Para. [0076].

Further, paragraphs [0100] and [0115] along with Figs. 7 and 19 disclose preparation of "the partially corrected upper and lower vertebrae" and insertion of a prosthetic joint between the partially corrected vertebrae. Similarly, paragraphs [0101], [0102], [0116], and [0117] along

with Figs. 8 and 10 disclose preparation of "fully corrected" vertebrae and insertion of a prosthetic joint between the fully corrected vertebrae. Clearly, Applicants intended the very method of correcting spondylolisthesis from a lateral approach described in the same section to be used to partially or fully correct the spondylolisthesis before introduction of the prosthetic joints. As noted by Applicants, "Spondylolisthesis has not heretofore been corrected from the lateral surgical approach." Para. [0078]. Thus, it is clear that the "Lateral Correction" portion of the application describing (1) the creation of the intervertebral space S for receiving a prosthetic joint, (2) the use of bone screws and a rod from a lateral approach to partially or fully correct spondylolisthesis, and (3) the lateral insertion of a prosthetic joint into the intervertebral space S after the partial or full correction of the spondylolisthesis satisfies the requirements of 35 U.S.C. §112, first paragraph. Accordingly, Applicants request that the §112 rejections of claims 14-16 and 31-40 be withdrawn.

C. Rejections under 35 U.S.C. §102

Claims 12, 13, 17, 21, 31-35, and 38 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,108,395 to Laurain ("the Laurain patent"). The PTO provides in MPEP § 2131 that

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. " Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... "The identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (emphasis added)

Therefore, to sustain the rejection of claims 12, 13, 17, 21, 31-35, and 38 the Laurain patent must disclose each and every element in as complete detail as recited in the claims.

First, as a preliminary matter, the Laurain patent entirely fails to disclose correcting spondylolisthesis. In that regard, there is no mention of spondylolisthesis anywhere in the Laurain patent. Rather, the Laurain patent is focused on "the correction of kyphoses caused by the destruction of one or two vertebral bodies." Thus, the Laurain patent necessarily fails to

disclose each and every element in as complete detail as recited in independent claims 12 and 31, which are directed to methods of correcting spondylolisthesis.

Further, with respect to independent claims 12 and 31, the Laurain patent at least fails to disclose "applying a rotating force directly to the connecting member from a substantially lateral approach after engagement of the connecting member with the first and second insertion members to rotate the first and second vertebrae relative to one another to reduce the spondylosed relationship therebetween." First, the Laurain patent explicitly notes that "[t]he subject of the present invention is an implant for **anterior** dorsolumbar spinal osteosynthesis," "the object of the invention is therefore to provide an implant having the advantages of these two categories of prior devices without having their disadvantages so as to carry out an **anterior** reconstruction of the dorso-lumbar spine," and "[t]he implant 1 [is] intended to be fitted **anteriorly** onto the vertebral bodies." Col. 1, ll. 6-9, Col. 2, ll. 31-36, and Col. 4, ll.13-14 (emphasis added).

Finally, the vertebrae in the Laurain patent are moved by distracting forceps, not by rotating the plate 6. Specifically, the Laurain patent states that "[t]he surgeon then fits the distracting forceps (FIG. 7), the tips 21a of which fit into the notches 23 against which they bear, so as to permit distraction and to correct the kyphosis." Col. 6, ll. 65-68. With respect to the plate 6 and clamps, the Laurain patent notes that "means for adjusting the angle of the plate 6 relative to the clamps 2 and for locking in rotation (complementary serrations 18 and 19) enable the implant to be fitted with a maximum amount of flexibility, and likewise adaptability to the anatomical conditions of the spinal segment in question." Col. 7, ll. 47-52. In other words, the clamps and plate are adjusted to the orientation of the vertebrae. The plate is simply not rotated to adjust the orientation of the vertebrae, let alone correct spondylolisthesis from a lateral approach as required by claims 12 and 31.

For at least these reasons, the Laurain patent fails to disclose each of the recited elements of independent claims 12 and 31. Claims 13, 17, 21, 32-35, and 38 depend from and further limit claims 12 and 31. Thus, for at least the same reasons the Laurain patent fails to disclose each of the recited elements of these claims as well. Thus, Applicants request that the §102 rejection of claims 12, 13, 17, 21, 31-35, and 38 be withdrawn.

D. Rejections under 35 U.S.C. §103

1. Laurain Patent

Claim 36 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Laurain patent. As shown above, however, the Laurain patent fails to disclose each of the elements of independent claim 31 from which claim 36 depends from and further limits. Accordingly, for at least the same reasons the Laurain patent fails to disclose or suggest all of the elements of claim 36. Thus, Applicants request that the §103 rejection of claim 36 over the Laurain patent be withdrawn.

2. Laurain, Jacobsen, and Conchy Patents

Claim 37 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Laurain patent in view of U.S. Patent No. 5,382,248 to Jacobson et al. ("the Jacobson patent") and U.S. Patent No. 6,749,612 to Conchy et al. ("the Conchy patent"). As shown above, the Laurain patent fails to disclose each of the elements of independent claim 31, from which claim 37 depends from and further limits. The Jacobson and Conchy patents do not affect this deficiency. Accordingly, even when combined the Laurain, Jacobson, and Conchy patents fail to disclose all of the recited elements of claims 37. Thus, Applicants request that the §103 rejection of claim 37 over the Laurain, Jacobson, and Conchy patents be withdrawn.

3. Thomas and Laurain Patents

Claims 31-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,964,665 to Thomas et al. ("the Thomas patent") in view of the Laurain patent.

The PTO provides in MPEP §2131 that

> "The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness."

The Examiner clearly cannot, using the Thomas and Laurain patents, establish a prima facie case of obviousness in connection to claims 12, 13, 17, 20, 21, and 31-35 for at least the following reasons.

35 U.S.C. §103(a) provides, in part, that:

> "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time of the invention was made to a person having ordinary skill in the art . . ." (emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated.

However, even when combined the Thomas and Laurain patents fail to disclose all of the recited limitations of independent claims 12 and 31. In that regard, the Office Action asserts that the Thomas patent discloses the recited limitations of these claims, except that the Thomas patent "fails to disclose that the spinal disc would need to be removed or to place an implant between the vertebrae." Applicants respectfully disagree.

First, with respect to independent claim 12, the Thomas patent clearly does not disclose "laterally inserting a first insertion member into a lateral sidewall of the first vertebra such that the first insertion member does not extend within the intervertebral space and does not engage a pedicle of the first vertebra; laterally inserting a second insertion member into a lateral sidewall of the second vertebra such that the second insertion member does not extend within the intervertebral space and does not engage a pedicle of the second vertebra" as recited. Similarly, with respect to independent claim 31, the Thomas patent fails to disclose "laterally inserting a first insertion member into a sidewall of the first vertebra such that the first insertion member does not extend within the intervertebral space and is spaced from a pedicle of the first vertebra; laterally inserting a second insertion member into a sidewall of the second vertebra such that the second insertion member does not extend within the intervertebral space and is spaced from a pedicle of the second vertebra," as recited.

Second, with respect to independent claim 12, the Thomas patent also fails to disclose "applying a rotating force directly to the connecting member from a substantially lateral approach after engagement of the connecting member with the first and second insertion members to rotate the first and second vertebrae relative to one another to reduce the spondylosed relationship therebetween" as recited. The Thomas patent simply does not disclose applying a rotating force to rods 50 to rotate the vertebrae relative to one another as asserted in the Office Action. Rather, the Thomas patent explicitly states that "[t]he alignment rods 10 are []

used to manipulate and align the vertebral body 52 to the desired angle and position ... the surgeon would ... pull or push the vertebral body to correct spondylolisthesis ... **Once the surgeon has manipulated the vertebral bodies into the proper, or desired, alignment**, the fixation hardware is slipped down the shaft of the alignment rod 10." Col. 6, Lines 37-67 (emphasis added). Applicants would point out that the alignment rods 10 that are utilized to adjust the position of the vertebral bodies do **not** extend between vertebrae as required of the connecting member of claims 12 and 31, but rather each alignment rod 10 is connected to a single vertebra. The rods 50 are then used to secure the vertebrae in position after positioning of the vertebrae with the alignment rods. Thus, the Thomas patent also fails to disclose the limitations of claim 31 requiring "applying a rotating force to the elongated member from a lateral approach to rotate the first and second vertebrae relative to one another to reduce the spondylosed relationship therebetween."

In addition, the Thomas patent fails to disclose applying a rotating force from a substantially lateral approach as required. Consistent with the drawings of the Thomas patent and the corresponding description explaining that a surgeon would "pull or push the vertebral body to correct spondylolisthesis," it is clear that the Thomas patent discloses only a substantially posterior approach to correcting spondylolisthesis. The Thomas patent clearly does not disclose the substantially lateral approach as required. The Office Action asserts that there must be some overlap between the "substantially lateral" approach recited in the claims and the "substantially posterior" approach disclosed by the Thomas patent. Applicants respectfully disagree. One skilled in the art certainly would not consider a substantially posterior approach as being a substantially lateral approach. While the term "substantially" as utilized in the claims does provide some variance to the lateral approach beyond a direct lateral approach, it still requires the approach to be substantially or mostly from the lateral direction. Similarly, a substantially posterior approach must be substantially or mostly from the posterior direction. Accordingly, one skilled in the art simply would not consider a substantially posterior approach to be a substantially lateral approach. Thus, the approach of the Thomas patent that is substantially posterior necessarily cannot be considered to disclose the substantially lateral approach recited in the claims.

Further, as noted above with respect to the §102 rejections, the Laurain patent fails to disclose the recited limitations of claims 12 and 31 as well.

Accordingly, for at least these reasons even when combined the Thomas and Laurain patents fail to disclose all of the recited elements of independent claims 12 and 31. Claims 13, 17, 20, 21, and 32-35 depend from and further limit claims 12 and 31. Thus, for at least these reasons Applicants request that the §103 rejection of claims 12, 13, 17, 20, 21, and 31-35 over the Thomas and Laurain patents be withdrawn.

4. Thomas, Laurain, and Marnay Patents

Claim 39 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over the Thomas and Laurain patents as applied to claim 31 in further view of U.S. Patent No. 5,314,477 to Marnay ("the Marnay patent"). As discussed above, even when combined the Thomas and Laurain patents fail to disclose all of the recited elements of independent claim 31 from which claim 39 depend. The Marnay patent does not affect this deficiency. Accordingly, for at least the same reasons the Thomas, Laurain, and Marnay patents fail to disclose all of the limitations of claim 39. Therefore, Applicants request that the §103 rejection of claim 39 over the Thomas, Laurain, and Marnay patents be withdrawn.

5. Jackson and Kapp Patents

Claims 12, 13, 17, 20, and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,591,165 to Jackson ("the Jackson patent") in view of U.S. Patent No. 4,554,914 to Kapp et al. ("the Kapp patent"). However, even when combined the Jackson and Kapp patents fail to disclose all of the recited limitations of claims 12, 13, 17, 20, and 21.

For example, with respect to independent claim 12, the Jackson patent fails to disclose "laterally inserting a first insertion member into a lateral sidewall of the first vertebra such that the first insertion member does not extend within the intervertebral space and does not engage a pedicle of the first vertebra; laterally inserting a second insertion member into a lateral sidewall of the second vertebra such that the second insertion member does not extend within the intervertebral space and does not engage a pedicle of the second vertebra," as recited. Instead, as clearly shown in Figs. 3-5, 9A, 9B, 9C, 11A, 11B, and 17A-20B of the Jackson patent, the bone

screws of the Jackson patent are introduced through the pedicles of the vertebrae. The Jackson patent entirely fails to disclose laterally inserting first and second insertion members into the lateral sidewalls of the first and second vertebrae as recited by claim 12.

Further, the Jackson patent fails to disclose "applying a rotating force directly to the connecting member from a substantially lateral approach after engagement of the connecting member with the first and second insertion members to rotate the first and second vertebrae relative to one another to reduce the spondylosed relationship therebetween." In that regard, Applicants disagree that the disclosure of rotating of a rod in the sagittal plane is rotation from a substantially lateral approach as required by claim 12. The Jackson patent notes that "This force application is possible with screws advanced through the pedicles from a posterior approach." Further, as noted above, Figs. 3-5, 9A, 9B, 9C, 11A, 11B, and 17A-20B of the Jackson patent illustrate the bone screws being introduced into the pedicles of the vertebrae from a posterior approach. There is simply no mention of utilizing a lateral approach in the Jackson patent. Thus, the Jackson patent necessarily fails to disclose the above-recited limitations of claim 12.

For at least these reasons, even when combined the Jackson and Kapp patents fail to disclose or suggest all of the recited limitations of independent claim 12. Claims 13, 17, 20, and 21 depend from and further limit claim 12. Thus, a *prima facie* case of obviousness has not been established with respect to claims 12, 13, 17, 20, and 21. Therefore, Applicants request that the §103 rejection of claims 12, 13, 17, 20, and 21 over the Jackson and Kapp patents be withdrawn.

6. Jackson, Kapp, and Marnay Patents

Claims 14-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Jackson and Kapp patents as applied to claim 13 in further view of the Marnay patent. As discussed above, even when combined the Jackson and Kapp patents fail to disclose all of the recited elements of independent claim 12 from which claims 14-16 depend and further limit. The Marnay patent does not affect this deficiency. Accordingly, for at least the same reasons the Jackson, Kapp, and Marnay patents fail to disclose all of the limitations of claims 14-16. Therefore, Applicants request that the §103 rejection of claims 14-16 over the Jackson, Kapp, and Marnay patents be withdrawn.

7. Jackson, Kapp, and Wagner Patents

Claims 18 and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson and Kapp patents as applied to claim 17 in view of U.S. Patent No. 6,030,389 to Wagner et al. ("the Wagner patent"). As shown above, however, even when combined the Jackson and Kapp patents fail to disclose all of the elements of independent claim 12, from which claims 18 and 19 depend from and further limit. The Wagner patent does not affect this deficiency. Accordingly, even when combined the Jackson, Kapp, and Wagner patents fail to disclose all of the recited elements of claims 18 and 19. Thus, Applicants request that the §103 rejection of claims 18 and 19 over the Laurain and Wagner patents be withdrawn.

8. Jackson, Kapp, Marnay, Jacobson, and Conchy Patents

Claim 40 stands rejected under 35 U.S.C. §103(a) as being unpatentable over a combination of the Jackson, Kapp, Marnay, Jacobson, and Conchy patents. However, as discussed above with respect to independent claim 12, the Jackson patent fails to disclose "inserting a first bone screw into a lateral sidewall of the first vertebra via a lateral approach; inserting a second bone screw into a lateral sidewall of the second vertebra via a lateral approach," as recited. The Jackson patent also fails to disclose "rotating the rod from a lateral approach to adjust the positions of the first and second vertebrae relative to one another to reduce the spondylosed relationship therebetween." Further, none of the other references discloses these limitations either. Accordingly, even when combined the Jackson, Kapp, Marnay, Jacobson, and Conchy patents fail to disclose all of the recited limitations of independent claim 40. Thus, Applicants request that the §103 rejection of claim 40 over the Jackson, Kapp, Marnay, Jacobson, and Conchy patents be withdrawn.

IV. Conclusion

It is believed that all matters set forth in the Office Action have been addressed and that all pending claims are in condition for allowance. Accordingly, Applicants request an indication of allowance of the pending claims.

The Office Action contains characterizations of the claims and the related art to which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in this or any other Office Action.

If an interview would expedite prosecution in any way, the Examiner is invited to contact the Applicants' undersigned representative.

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Date: 1-28-09

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